AMENDMENTS TO THE CLAIMS

Docket No.: 37998-237524

1. (Currently Amended) A method of preparing a purified, virus inactivated and virus safe

antibody preparation from a starting solution comprising antibodies and contaminants, the method

comprising the steps of:

(a) adjusting the pH of the starting solution to about 4.6 4.8 to about 4.95, to produce an

intermediate solution;

(b) adding caprylate and/or heptanoate ions to the intermediate solution and maintaining the pH at

about 4.8 to about 4.95, whereby a precipitate is formed and the antibodies are essentially present in

a supernatant;

(c) incubating the supernatant solution under conditions of caprylate and/or heptanoate ion

concentration, time, pH and temperature to achieve precipitation of non-IgG proteins and filtering

the solution:

(d) applying the filtered solution to at least one a first chromatographic column filled with a first

anion exchange resin at a pH from about 5.0 to about 5.2 under conditions that allow binding of

contaminants to the resin while not allowing significant binding of the antibodies to the resin,

wherein a purified, virus inactivated and virus safe antibody preparation is produced as

flow-through.

2. (Cancelled)

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(Currently Amended) The method of claim 1 further comprising performing a second anion

exchange chromatography at a pH range of from about 6.7 to about 6.9.

4. (Previously Presented) The method of claim 1 wherein steps (b) and (c) are repeated at least

one time.

3.

5 (Previously Presented) The method of claim 1 wherein the starting solution comprises

plasma-derived antibodies.

6. (Currently Amended) The method of claim 1 wherein step (d) is performed using two

different anion exchange resins further comprising applying the flow-through of the

chromatographic column to a second chromatographic column filled with a second anion exchange

resin to perform a second chromatography under conditions that allow binding of contaminants to

the resins while not allowing significant binding of the antibodies to the resins.

7. (Previously Presented) The method of claim 1, wherein the antibodies are immunoglobulin

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8. (Currently Amended) The method of claim 6, where the pH is adjusted to about pH 6.8 6.7

to 6.9 prior to the second anion-exchange chromatography.

9. (Currently Amended) The method of claim 1 further comprising concentrating the anion-

exchange chromatography flow-through to about 60 to about 90 mg/ml and diafiltrating the anion-

exchange chromatography flow-though against a buffer solution.

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- 10. (Currently Amended) The method of claim further comprising treating the flow-through of the first anion-exchange chromatography with solvent detergent for about 4.5 to about 8 hours to inactivate lipid coated viruses.
- 11. (Previously Presented) The method of claim 10, further comprising removing the detergents of the incubation mixture by solid and liquid phase extraction.
- 12. (Previously Presented) The method of claim 1 further comprising combining the caprylate treatment with one or more of the following-UV-C treatment, heat-treatment, virus filtration, and prion removal or inactivation.
- 13. (Currently Amended) The method of claim 11, further comprising adjusting the pH value upon solid phase extraction to about 6.7 to about 6.9.
- 14. (Previously Presented) The method of claim 13, further comprising submitting the solution to the second anion-exchange chromatography.
- 15. (Currently Amended) The method of claim 14, further comprising adjusting the pH value of the <u>second</u> anion-exchanger flow-through to about 3.5 to about 4.5.
- 16. (Previously Presented) The method of claim 15, wherein the antibodies are IgG and further comprising contacting the IgG solution by a virus filter.
- 17. (Previously Presented) The method of claim 15, wherein the antibodies are IgG and further comprising contacting the IgG solution by a nanofilter.

18. (Previously Presented) The method of claim 15 wherein the antibodies are IgG and further comprising incubating the IgG solution for at least 24 hours.

19. (Currently Amended) The method of claim 15, wherein the antibodies are IgG and further

comprising concentrating the IgG solution to about 5 or about 10% (w/v) to form a concentrate.

20. (Currently Amended) The method of claim 19, wherein the osmolarity of the concentrate is

about 200 to about 400 mOsmol/kg.

21. (Currently Amended) The method of claim 20, further comprising adjusting the pH of the

IgG solution concentrate to about 3.5 to about 6.0.

22. (Currently Amended) The method of claim 21 further comprising sterile filtering and filling

the IgG solution concentrate in glass bottles or plastic containers.

23. (Cancelled).

24. (Previously Presented) The method of claim 9 wherein the buffer solution is a phosphate

buffer solution.

25. (Previously Presented) The method of claim 10 wherein the solvent detergent is Triton X-

100 and TnBP.

26. (Previously Presented) The method of claim 25 wherein the concentration is 1% Triton and

0.3% TnBP.

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27. (Currently Amended) The method of claim 15, wherein the pH of the second anion-exchanger flow-through is about 4.0.

28. (Currently Amended) The method of claim 18, wherein the incubation temperature is about 37° C $\pm \frac{1}{2}$ °C.